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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,416	06/30/2003	Alfred Korber	45384	8050

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	
MAIL DATE	**DELIVERY MODE**
07/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,416	KORBER, ALFRED	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7,10,11 and 13-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,10,11 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 7, 10 and 11 are directed to the process of making or using the product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 06/28/06 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-7, 10, 11 and 13-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 7-11, 14 and 15 of copending Application No. 10/516005 ('005), in view of US 2003/0235545 ('545). Although the conflicting claims are not identical, they are not patentably distinct from each other because application '005 claims a menthol molding comprising alpha-menthol, wherein the concentration of alpha-menthol in the molding is at least 90 wt. % (claims 1 and 5). Spheres, cubes, cuboids, cushions, cylinders, tablets, pellets or briquettes are found in claim 7. A process comprising compacting the material with pressing in the range of 10-100 kN is found in claims 7-11, 14 and 15. Application '005 does not require the use of inorganic salt stabilizer, or the use of alkali (earth) metal carbonate/bicarbonate.

It is noted that application '005 does not recite the claimed cooling agent such as menthyl lactate. However, US '545 teaches cooling agent includes agent selected from the group of l-menthol and menthyl lactate (abstract; and paragraph 0005). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation

select menthyl lactate as a cooling agent in view of the teaching of the US '545, because US '545 teaches the equivalency between menthyl lactate and l-menthol.

Further, it is noted that application '005 does not specifically recite the claimed storage stability. However, application '005 teaches the use of similar cooling agent, in the claimed amount, and compacted in the claimed shape. The burden is shifted to applicant to show that the composition of the '005 application does not result in the claimed storage stable.

Accordingly, the present claims would have been obvious given the claims of the '005 application in view of US '545, which set out a similar compact dosage for cooling agent using the similar materials, steps, and conditions as claimed herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eis et al. WO 95/07683, in view of Serpelloni US 7,201,922.

Eis teaches a composition comprising from about 75% to about 99.999% of carrier material including coolants such as menthyl lactate (abstract; page 4, 1st

paragraph; and page 7, 2nd paragraph). The composition can be compressed into tablet (page 10, 2nd paragraph).

Eis does not expressly teach the claimed compression force. However, Serpelloni teaches compressed tablet prepared by applying compression force of at least 13.4 kN (table 5). Thus, it would have been obvious to one of ordinary skill in the art to prepare the tablet of Eis using compressed force in view of the teaching of Serpelloni to obtain the claimed invention. This is because Serpelloni teaches using the claimed compressed force to prepare a compressed dosage form is well known in pharmaceutical art, because Serpelloni teaches using a compressed force within the claimed range to obtain tablet having pharmaceutically acceptable hardness, and because Eis teaches tablet dosage forms using a compressed method.

It is noted that Eis does not explicitly teach the claimed storage stability. However, the burden is shifted to applicant to show that the compressed tablet of Eis does not exhibit the claimed storage stability. This is because Eis teaches the use of the claimed coolant in the claimed amount in a compressed dosage form. Accordingly, the use of the same ingredients would necessitate the claimed properties. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 1, 6 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kajs et al. US 5,397,573, in view of Eis et al. WO 95/07683 and Serpelloni US 7,201,922.

Kajs teaches a laxative composition comprising from about 1% to about 99% menthol (abstract; and column 3, lines 7-65). The composition is formulated into solid dosage forms including tablet (column 4, lines 19-25).

Kajs does not explicitly teach the claimed coolant such as menthyl lactate. However, Eis teaches coolants include menthol or menthyl lactate (page 3, last paragraph through page 4, 1st paragraph). Thus, it would have been obvious to one of ordinary skill in the art to modify the laxative composition of Kajs using menthyl lactate as a coolant in view of the teaching of Eis, because Eis teaches menthyl lactate is a well known coolant in pharmaceutical art, because Eis teaches the equivalency between menthol and menthyl lactate, and because Kajs teaches the use of menthol or pharmaceutically acceptable esters of menthol such as menthol acetate.

It is noted that the references do not expressly teach the claimed compression force. However, Serpelloni teaches compressed tablet prepared by applying compression force of at least 13.4 kN (table 5). Thus, it would have been obvious to one of ordinary skill in the art to prepare the tablet of Kajs in view of Eis using compressed force taught by Serpelloni to obtain the claimed invention. This is because Serpelloni teaches using the claimed compressed force to prepare a compressed dosage form is well known in pharmaceutical art, because Serpelloni teaches using a compressed force within the claimed range to obtain tablet having pharmaceutically

acceptable hardness, and because Kajs teaches tablet dosage prepared by any known method in pharmaceutical art.

It is noted that Kajs does not explicitly teach the claimed storage stability. However, the burden is shifted to applicant to show that the compressed tablet of Kajs in view of Eis does not exhibit the claimed storage stability. This is because Eis teaches the use of the claimed coolant in a compressed dosage form. Accordingly, the use of the same ingredients would necessitate the claimed properties. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 4, 5, 7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eis et al. WO 95/07683, in view of Serpelloni US 7,201,922 and Kuhn et al. US 5,783,725.

Eis is relied upon for the reasons stated above. Eis does not expressly teach the claimed menthyl lactate such as L-lactic acid L-menthyl ester having purity of at least 95%.

Kuhn teaches a stable lactic acid menthyl ester comprising L-lactic acid L-menthyl ester having purity of 99.7% (abstract; and column 2, lines 42-44). Thus, it would have been obvious to one of ordinary skill in the art to prepare the dosage form of

Eis using the menthyl lactate in view of the teaching of Kuhn to obtain the claimed invention. This is because Kuhn teaches a menthyl lactate that is shelf stable for several months with no changes in smell, because Kuhn teaches the use of menthyl lactate as a cooling agent in pharmaceutical preparations (column 1, lines 5-53), and because Eis teaches the use of menthyl lactate as a cooling agent in a pharmaceutical composition to obtain a formulation useful in pharmaceutical art.

Claims 4, 5, 7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kajs et al. US 5,397,573, in view of Eis et al. WO 95/07683 and Serpelloni US 7,201,922 and Kuhn et al. US 5,783,725.

Kajs is relied upon for the reasons stated above. Kajs does not expressly teach the claimed menthyl lactate such as L-lactic acid L-menthyl ester having purity of at least 95%.

Kuhn teaches a stable lactic acid menthyl ester comprising L-lactic acid L-menthyl ester having purity of 99.7% (abstract; and column 2, lines 42-44). Thus, it would have been obvious to one of ordinary skill in the art to prepare the dosage form of Kajs using menthyl lactate as a cooling agent in view of the teaching of Kuhn to obtain the claimed invention. This is because Kuhn teaches menthyl lactate having cooling action desired for pharmaceutical preparations, Kuhn teaches a menthyl lactate that is shelf stable for several months with no changes in smell (column 1, lines 5-53), and because Kajs teaches the desirability of using a cooling agent in formulations useful in pharmaceutical art.

Response to Arguments

Applicant's arguments with respect to the present claims have been considered but are moot in view of the new grounds of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1615

SUSAN TRAN
PRIMARY EXAMINER